

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Xianzhang YU, et al.

Title: LYTIC PEPTIDE PRODRUGS

Appl. No.: 09/938,623

Filing Date: 08/27/2001

Examiner: Unassigned

Art Unit: 1644



TECH CENTER 1600/2900

JAN 23 2002

RECEIVED

INFORMATION DISCLOSURE STATEMENT
UNDER 37 CFR §1.56

Commissioner for Patents
Washington, D.C. 20231

Sir:

Submitted herewith on Form PTO-SB-08 is a listing of documents known to Applicants in order to comply with Applicants' duty of disclosure pursuant to 37 CFR §1.56. A copy of each listed document is being submitted to comply with the provisions of 37 CFR §1.97 and §1.98.

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicants do not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* art reference against the claims of the present application.

TIMING OF THE DISCLOSURE

The listed documents are being submitted in compliance with 37 CFR §1.97(b), before the mailing date of the first Office Action on the merits.

RELEVANCE STATEMENTS

The relevance of Documents A1-A31 is described in the present specification.

Applicants respectfully request that any listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO-SB-08 be returned in accordance with MPEP §609.

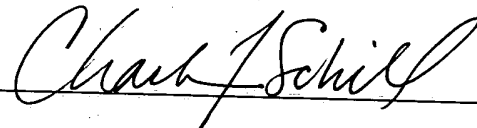
The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741.

Respectfully submitted,

Date January 15, 2002

FOLEY & LARDNER
Washington Harbour
3000 K Street, N.W., Suite 500
Washington, D.C. 20007-5143
Telephone: (202) 945-6078
Facsimile: (202) 672-5399

By



Charles F. Schill
Attorney for Applicant
Registration No. 27,590

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449B/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Application Number	09/938,623
				Filing Date	08/27/2001
Date Submitted: December 28, 2001				First Named Inventor	Xianxhang YU, et al.
(use as many sheets as necessary)				Group Art Unit	1644
Sheet 1 of 3				Examiner Name	Unassigned
				Attorney Docket Number	035879-0125

U.S. PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Code ² (if known)			
	A1	6,255,282	B1	JAYNES	07/03/01	

FOREIGN PATENT DOCUMENTS								
Examiner Initials*	Cite No. ¹	Foreign Patent Document			Name of Patentee or Applicant of Cited Documents	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Office ³	Number ⁴	Kind Code ⁵ (if known)				
	A2	PCT	97/33908		RIVETT et al.			

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS				
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.		T ⁶
	A3	BLONDELLE et al., "Hemolytic and Antimicrobial Activities of the Twenty-Four Individual Omission Analogues of Melittin," <i>Biochemistry</i> , 1991, pp. 4671-4678, Vol. 30, American Chemical Society.		
	A4	DEMPSEY et al., "Contribution of Proline-14 to the Structure and Actions of Melittin," <i>FEBS Letters</i> , 1991, pp. 240-244, Vol. 281, No. 1,2, Elsevier Science Publishers B.V.		
	A5	LEIPPE et al., "Cytolytic and Antibacterial Activity of Synthetic Peptides Derived from amoebapore, the Pore-Forming Peptide of <i>Entamoeba Histolytica</i> ," <i>Proc. Natl. Acad. Sci. USA</i> , 1994, pp. 2602-2606, Vol. 91, Federation of European Biochemical Societies.		
	A6	ANDRÁ et al., "Shortened Amoebapore Analogs with Enhanced Antibacterial and Cytolytic Activity," <i>FEBS Letters</i> , 1996, pp. 96-100, Vol. 385, Federation of European Biochemical Societies		

Examiner Signature	Date Considered
--------------------	-----------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.

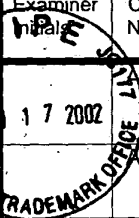
⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, D.C. 20231.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449B/PTO		Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT		Application Number	09/938,623
		Filing Date	08/27/2001
Date Submitted: December 28, 2001 (use as many sheets as necessary)		First Named Inventor	Xianzhang YU, et al.
		Group Art Unit	1644
Sheet 2 of 3		Examiner Name	Unassigned
		Attorney Docket Number	035879-0125

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

Examiner Initials	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ⁶
	A7	SHAI et al., "Diastereomers of Cytolysins, a Novel Class of Potent Antibacterial Peptides," <i>Journal Biological Chemistry</i> , 1996, pp. 7305-7308, Vol. 271 No. 13, The American Society for Biochemistry and Molecular Biology, Inc.	
	A8	WERKMEISTER et al., "The Effect of Sequence Variations and Structure on the Cytolytic Activity of Melittin Peptides," <i>Biochimica et Biophysica Acta</i> , 1993, pp. 50-54, Vol. 1157, Elsevier Science Publishers B.V.	
	A9	LEIPPE et al., "Pore-Forming Peptide of Pathogenic <i>Entamoeba Histolytica</i> ," <i>Proc. Natl. Acad. Sci. USA</i> , 1991, pp. 7659-7663, Vol. 88, Federation of European Biochemical Societies.	
	A10	HOROSZEWICZ et al., "LNCaP Model of Human Prostatic Carcinoma ¹ ," <i>Cancer Research</i> , 1983, pp. 1809-1818, Vol. 43, No. 4, American Association for Cancer Research.	
	A11	PINTO et al., "Prostate Specific Membrane Antigen, a Unique Glutamate Carboxypeptidase: A Review of Recent Findings," <i>The Prostate Journal</i> , 1999, pp. 15-26, Vol. 1, No. 1, Blackwell Science, Inc.	
	A12	LOPES et al., "Immunohistochemical and Pharmacokinetic Characterization of the Site-Specific Immunoconjugate CYT-356 Derived from Antiprostate Monoclonal Antibody," <i>Cancer Research</i> , 1990, pp. 6423-6429, Vol. 50, American Association for Cancer Research.	
	A13	TROYER et al., "Detection and Characterization of the Prostate-Specific Membrane Antigen (PSMA) in Tissue Extracts and Body Fluids," <i>Int. J. Cancer</i> , 1995, pp. 552-558, Vol. 62, Wiley-Liss, Inc.	
	A14	WALLRAPP et al., "A Novel Transmembrane Serine Protease (TMPRSS3) Overexpressed in Pancreatic Cancer ^{1,2} ," <i>Cancer Research</i> , 2000, pp. 2602-2606, Vol. 60, No. 10, American Association for Cancer Research.	
	A15	WRIGHT et al., "Expression of Prostate-Specific membrane Antigen in Normal, Benign, and Malignant Prostate Tissues," <i>Urol. Oncol.</i> , 1995, pp. 18-28, Vol. 1, Elsevier Science Inc., New York.	
	A16	PRAUSNITZ et al., "Electroporation of Mammalian Skin: A Mechanism to Enhance Transdermal Drug Delivery", <i>Proc. Natl. Acad. Sci. USA</i> , 1993, pp. 10504-10508, Vol. 90, No. 22, Medical Sciences, NIH	
	A17	WALLACE et al., "Stand and Deliver: Getting Peptide Drugs into the Body", <i>Science</i> , 1993, pp. 912-913, Vol. 260, American Association for the Advancement of Science	
	A18	ANDREU et al., "Solid-Phase Synthesis of Cecropin A and Related Peptides", <i>Proc. Natl. Acad. Sci. USA</i> , 1983, pp. 6475-6479, Vol. 80, No. 21, Biochemistry, Biological Science	
A19	ANDREU et al., "N-Terminal Analogues of Cecropin A: Synthesis, Antibacterial Activity, and Conformational Properties", <i>Biochemistry</i> , 1985, pp. 1683-1688, Vol. 24, No. 7, American Chemical Society		
A20	FINK et al., "Design, Synthesis and Antibacterial Activity of Cecropin-Like Model Peptides", <i>Int. J. Peptide Protein Res.</i> , 1989, pp. 412-421, Vol. 33, No. 6, The Rockefeller University, New York, New York		

Examiner
Signature

Date
Considered

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

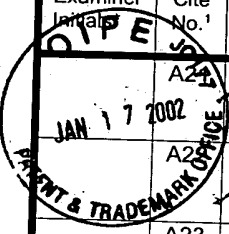
¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.

⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, D.C. 20231.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449B/PTO		Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT Date Submitted: December 28, 2001 (use as many sheets as necessary)		Application Number	09/938,623
		Filing Date	08/27/2001
		First Named Inventor	Xianzhang YU, et al.
		Group Art Unit	1644
		Examiner Name	Unassigned
		Attorney Docket Number	035879-0125
Sheet	3	of	3

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ⁶
	A24	FINK et al., "The Chemical Synthesis of Cecropin D and an Analog with Enhanced Antibacterial Activity", J. of Biological Chemistry, 1989, pp. 6260-6267, Vol. 264, No. 11, American Society for Biochemistry and Molecular Biology, Inc. Rockefeller University, New York	
	A22	ARGIOLAS et al., "Bombolitins, a New Class of Mast Cell Degranulating Peptides from the Venom of the Bumblebee Megabombus Pennsylvanicus", J. of Biological Chemistry, 1985, pp. 1437-1444, Vol. 260, No. 3, American Society of Biological Chemists, Inc.	
	A23	YOUNG et al., "Characterization of a Member Pore-Forming Protein From Entamoeba Histolytica", J. Exp. Med. 1982, pp. 1677-1690, Vol. 156, No. 6, The Rockefeller University Press	
	A24	LYNCH et al., "An Ion-Channel Forming Protein Produced by Entamoeba Histolytica", The EMBO Journal, 1982, pp. 801-804, Vol. 1, No. 7, IRL Press Limited, Oxford, England	
	A25	YOUNG et al., "Molecular Mechanisms of Cytotoxicity Mediated by Entamoeba Histolytica: Characterization of a Pore-Forming Protein (PFP)", J. of Cellular Biochemistry, 1985, pp. 299-308, Vol. 29 No. 4, Alan R. Liss, Inc.	
	A26	ROSENBERG et al., "Isolation, Characterization and Partial Purification of a Transferable Membrane Channel (Amoebapore) Produced by Entamoeba Histolytica", Molecular and Biochemical Parasitology, 1989, pp. 237-248, Vol. 33, No. 3, Elsevier Science Publishers B.V.	
	A27	JANSSON et al., "Coding of Hemolysins Within the Ribosomal RNA Repeat on a Plasmid in Entamoeba Histolytica", Science, 1994, pp. 11440-1443, Vol. 263, American Association for the Advancement of Science	
	A28	FERNANDEZ-LOPEZ et al., "Antibacterial Agents Based on the Cyclic D,L- α -Peptide Architecture", Letters of Nature, 2001, pp. 452-455, Vol. 412	
	A29	WOODLE et al., "Prolonged Systemic Delivery of Peptide Drugs by Long-Circulating Liposomes: Illustration with Vasopression in the Brattleboro Rat", Pharmaceutical Research, 1992, pp. 260-265, Vol. 9, No. 2, Plenum Publishing Corporation	
	A30	HUSE et al., "Generatio of a Large Combinatorial Library of the Immunoglobulin Repertoire in Phage Lambda", Science, 1989, pp. 1275-1281, Vol. 246, Research Article	
A31	COOMBS et al., "Substrate Specificity of Prostate-Specific Antigen (PSA)", Chemistry & Biology, 1998, pp. 475-488, Vol. 5, No.9, Research Paper		

Examiner Signature	Date Considered
--------------------	-----------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1 Unique citation designation number. 2See attached Kinds of U.S. Patent Documents. 3Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 4For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 5Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. 6Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, D.C. 20231.